REMARKS

Claims 7, 8, 13, and 17 are currently pending and claims 1-6, 9-12, 14-16 and 18-36 have been canceled without prejudice with the right to re-introduce such claims in the instant application or in a future application claiming benefit of priority to the captioned application. Claims 37-49 have been withdrawn.

A new abstract has been presented. Support for the abstract can be found throughout the specification at, for example, page 3, line 29 – page 4, line 7 and the Examples. It is submitted that no new matter has been added by the above amendments.

Objection

The amendment filed on 11/2/01 (preliminary amendment) was objected to under 35 USC § 132 "because it introduces new matter into the disclosure." (Paper No. 20040423 ("Office Action") at 2.)

The Examiner contended that "when only lactase and microcrystalline cellulose are present, a preblend rather than a tablet exists." (Office Action at 2-3.) The Examiner observed that "the preblend is not disclosed as containing the amount of lactase and microcrystalline cellulose in the abstract." (*Id.* at 3.) The Examiner also observed that the "specification fails to support any mixture of the members of the Markush group of lines 5-7 of the abstract resulting from the abstract reciting 'and mixtures thereof.'" (*Id.*) The Examiner suggested submitting a new abstract. (*Id.*)

The Examiner's comments are well taken and a new abstract is submitted herewith in an attempt to address the Examiner's objections. It is submitted that the current abstract is believed to be fully supported and that no new matter has been introduced by the new abstract.

Written Description Rejection

Claim 32 was rejected under 35 USC §112, first paragraph, as containing subject matter that was not described in the specification in such a way to convey that the inventors, at the time the application was filed, had possession of the claimed invention. (Office Action at 3.) In making the rejection, the Examiner contended that "[t]he specification fails to support a range of 'about 0.25 to about 5%' by weight of lubricant."

(Id.) The Examiner asserted that "there is adequate support for only 'about 0.25 to about 6% by weight' lubricant."

While the Examiner's position is not agreed with, claim 32 has been cancelled without prejudice. Because claim 32 is no longer pending in the captioned application, it is believed that the instant rejection is moot and should, therefore, be withdrawn.

Obviousness Rejection

Claims 7, 8, 13, 17, 22, 23, 28, and 32 were rejected under 35 USC §103(a) as being unpatentable over US Pat. No. 3,718,739 ("Cayle") in view of U.S. Pat. No. 4,034,035 ("Schwartz") and U.S. Pat. No. 3,954,979 ("Bowman"). (Office Action at 4.)

For the reasons set forth below the rejection, respectfully is traversed.

Claims 22, 23, 28, and 32 have been cancelled without prejudice. Therefore, the rejections as to those claims are moot and should be withdrawn.

Cayle discloses an acid-active, acid-stable lactase enzyme preparation having at least 50,000 Lactase Units per gram of enzyme preparation. (Col. 2, lns. 7-16.) The above lactase enzyme preparation can be provided in unit dosage forms or in solutions, suspensions, and dispersions. (Col. 3, lns. 55-61.) In preparing solid compositions of the lactase enzyme preparation, Cayle discloses that preparing a tablet form, the lactase enzyme preparation is "mixed with conventional solid fillers or carriers such as cornstarch, talc, calcium phosphate, calcium sulfate, calcium stearate, magnesium stearate, steric acid, glyceryl mono- and distearate, sorbitol, manitol, gelatin, natural or synthetic gums, such as, carboxymethyl cellulose, methyl cellulose, alginate, dextran, acacia gum, karaya gum, locust bean gum, tragacanth and the like, diluents, binders, lubricants, disintegrators, coloring and flavoring agents." (Col. 3, ln. 62 – col. 4, ln. 6.)

Liquid forms disclosed by Cayle can be prepared using conventional liquid carriers such as glycerol and edible glycols, edible oils such as cottonseed oil, soybean oil, corn oil, peanut oil, safflower oil and other triglyceride oils, dispersing or suspending agents such as the above natural and artificial gums and various other diluents and vehicles. (Col. 4, lns. 7-17.)

The quantity of lactase enzyme preparation employed in the total oral dosage form can vary within wide limits. (Col. 4, lns. 31-39.) But, is present in an amount to provide for hydrolyzing lactose normally present or normally produced by the subject

requiring the lactase supplement. (Col. 4, lns. 40-45.) In particular, Cayle appears to disclose using 50,000 lactase units ("LU") in a lot of 100 tablets. (Examples 1 and 6.) Such tablets were produced from a formulation mixture containing 2 wt. % lactase[1], i.e., 500 LU/tablet (50,000 LU/ 100tablets) (Example 6).

Schwartz discloses a multitoned compressed tablet dosage form having a distinctive speckled (variegated) color by a controlled and easily reproducible process which involves only a single granulating and coloring step and which may be carried out with conventional tableting apparatus. (Col. 2, lns. 16-21.) Schwartz discloses that the excipient mixture employed in forming the granulation is a critical aspect that is essential to achieving the multitoned effect in the finished compressed tablet. (Col. 2, lns.45-48.) In particular, Schwartz discloses that the microcrystalline cellulose employed in the excipient mixture is a standard article of commerce that is well-known to those skilled in the art. (Col. 2, lns. 48-50.) Additionally, Schwartz discloses that modified corn starches suitable as excipient materials are those modified corn starches characterized by having a cold water solubles content in excess of 10% by weight. (Col. 2, lns. 53-57.) Finally, Schwartz discloses that no additional excipient is required in order to form granules suitable for compression and the microcrystalline cellulose and modified corn starch may be employed as obtained commercially without further modification. (Col. 2, lns. 64-68.) Schwartz discloses that a weight ratio of about 1:3 to 3:1 of microcrystalline cellulose to modified corn starch usually provides satisfactory results. (Col. 3, lns. 4-6.) Tablets made according to Schwartz were made using conventional wet-granulation techniques. (Co. 4, lns. 7-11.)

Bowman discloses a process for preparing a yeast and vitamin composition that is suitable for addition to certain diluents to form a granulation, which may be tableted without the use of added moisture, heat and certain conventional tableting aids. (Col. 3,

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[1] Cayle Example 6 states "[a] lot of 100 tablets for oral use, each containing 0.5 gram of the lactase enzyme preparation produced in accordance with Example 1 is produced from the following materials." Those following materials include only **1.0** gram of lactase (50,000 LU). 1.0 gram of lactase cannot make 100 tablets having 0.5 gram of lactase, as asserted in Example 6. Thus, it is believed that the 0.5 gram referred to was from the 50 gram formulation mixture in Example 6. The Examiner is asked to set forth any disagreement with this position in the next paper entered by the Examiner in this application.

lns. 5-9.) According to Bowman, the diluents and excipients consist of starch, such as corn or potato starch, microcrystalline cellulose and mixtures thereof. (Col. 4, lns. 23-27.) Bowman discloses that these materials, particularly mixtures of starch and microcrystalline cellulose in ratios form 20:80 to 80:20 are preferred. (Col. 27-29.) In addition, Bowman discloses that other additives can be employed that do not inactivate the enzymes in the yeast or the vitamins. (Col. 4, lns. 29-31.) Also required, according to Bowman, is that microcrystalline cellulose and starch are in dosage units in amounts of from 200 to 800 mg. microcrystalline cellulose and from 200 to 800 mg. of starch. (Col. 4, lns. 49-52.) Vegetable gum was also described as being also present in amounts of from 10 to 50 mg. in the dosage unit. (Col. 4, lns. 52-54.)

The process disclosed in Bowman was described as being a process for tableting compositions that do not require a wet granulation or drying step and produces a tableted product. (Col. 5, lns. 12-15.) Bowman's process requires forming a uniform admixture of aqueous yeast cream, nonreactive vegetable gum binder, and the vitamins, thiamine, riboflavin and niacin. (Col. 3, lns. 24-28.) The admixture is dehydrated under conditions that reduce the moisture content but does not inactivate the enzymes in the yeast or the vitamin components. (Col. 3, lns. 29-31.) The dehydrated product is ground under low temperature conditions to produce a uniform granular product. (Col. 3, lns. 32-34.) The granular dried product is then admixed with a diluent selected starch, microcrystalline cellulose and mixtures thereof, in the absence of heat and moisture to form a tableting blend. (Col. 3, lns. 35-39.) The tableting blend is then formed into tablets. (Col. 3, ln. 40.)

In making the rejection, the Examiner asserted that Cayle "discloses making tablets containing lactase." (Office Action at 4.) In particular, the Examiner asserted that Cayle discloses "[a] composition from which the tablet is made contains lactase mixed with conventional solid fillers or carriers, such as cornstarch, talc, calcium phosphate and calcium sulfate." The Examiner further contended that tablets are disclosed in Example 6 containing lactase, cornstarch, magnesium stearate and gelatin.

The Examiner asserted that Schwartz discloses preparing tablets having a lubricant, a mixture of microcrystalline cellulose and modified cornstarch in a ratio of about 1:3 to 3:1 and an enzyme.

The Examiner then asserted that Bowman discloses "dehydrating an admixture of yeast and vitamins under conditions that do not inactivate enzymes in the yeast, grinding the dehydrated product to produce a granular product, admixing the dried granular product with a diluent , and forming the resultant dry beend into tablets." The Examiner further asserted that the diluent can be selected from corn or potato starch, microcrystalline cellulose and mixtures thereof, and is preferably a mixture of starch and microcrystalline cellulose in a ration of 20:80 to 80:20. (*Id.* at 4-5.)

The Examiner then concluded that "it would have been obvious to replace a portion of the cornstarch in the lactase-containing tablet of Cayle with microcrystalline cellulose as suggested by Schwartz and Bowman." The Examiner contended that using the ratio ranges of Schwartz and Bowman would have inherently resulted in an amount of microcrystalline cellulose claimed. The Examiner asserted that "1 gram of 50,000 LU lactase in Example 6 of Cayle would have inherently resulted in FCC lactase unites in the range of about 3000 to 9000 as claimed

At the outset, the Examiner used the wrong standard in making the instant rejection. The Examiner asserted that "it would have been obvious to mix micrcrystalline cellulose...." It is respectfully submitted that this is not the standard for determining obviousness. Binding precedent requires that a conclusion of obviousness be based on what would have been obvious **to one having ordinary skill in the art at the time of the invention**. This, the Examiner has not done. Therefore, the rejection is improper and should be withdrawn.

Furthermore, Cayle appears to disclose using 50,000 lactase units ("LU)" in a lot of 100 tablets – that is **only 500 LU/tablet.** The tablet of the claimed invention affirmatively requires from about 3000 to about 9000 FCC lactase units. In addition, it is not seen where Cayle suggests a tablet having any other level of LU other than that found in Example 6.

Schwartz does not close the gaps left by Cayle. Schwartz does not specifically disclose lactase, much less any particular amount of lactase. Indeed, Schwartz does not disclose any specific enzyme that **could** be used. Here, the Examiner has not provided ***any*** reason for ***why*** one of ordinary skill in the art would have picked lactase, to the

exclusion of all other enzymes, and incorporate that particular enzyme into the tablet as claimed.

Similarly, Bowman does not close the gaps left by Cayle alone and in view of Schwartz. Bowman does not specifically disclose lactase. Nor does Bowman disclose a desire to have any particular potency for any enzyme.

It is respectfully submitted that it is not seen where a disclosure of 500 LU tablets provides any motivation or suggestion for a tablet containing, among other things, from about 3000 to about 9000 FCC lactase units. Nor is it seen where Schwarts and/or Bowman provide the requisite motivation. Therefore, the rejection is improper and should be withdrawn.

Double Patenting

Claims 7, 8, 13, 15, 17, 22, 28, and 32 were rejected under the judicially created doctrine of obviousness-type double patenting as being unapatentable over claims 1-11 of US Pat. No. 6,365,208 or claims 1-8 of US Pat. No. 6,057,139 in view of Schwartz and Bowman, and if necessary, in further view of Cayle. (Paper No. 7 at 7.)

Claims 22, 23, 28, and 32 have been cancelled without prejudice. Therefore, the rejections as to those claims are moot and should be withdrawn.

In making the rejection, the Examiner asserted that the claims of the patents require a formulation containing lactase and microcrystalline cellulose and the second bases of rejection was based on the Examiner's assertion that it would have been obvious to provide this formulation in tablet form for reasons previously set forth regarding application of Schwartz, Bowman and Cayle.

Upon notification by the Examiner that claims 7, 8, 13, 15, and 17 are allowable but for this rejection, the option of filing a Terminal Disclaimer will be addressed.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections and objections, and allowance of the claims is respectfully requested.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and

suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP § 707.07(j) or in making constructive suggestions pursuant to MPEP § 706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,

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